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Final Status of CDSCO/R/T/21/00110

Applicant Name	Vikas Patni
Date of receipt	15/04/2021
Request Filed With	CENTRAL DRUGS STANDARD CONTROL ORGANISATION
Text of Application	Provide me full info reagring vaccine, vaccination on rsepective 12 points below- 1 what are the contents of vaccines and how is it made ? 2 How much is the expiry date of corona vaccine from the date of manufacturing which is best for possible results ? 3 Is taking corona vaccine is mandatory ? 4 Under which rule or law any person without vaccination getting restiriction from goverments and companies for traveling, movement, services or compulsory for jobs, workers and service ? 5 Does vaccines gives gurranty that one should not have corona after taking two doses? 6 Is vaccine provides lifetime protection from corona after taking two doses or it have any time limit? 7 Does corona vaccine should be taken every year if corona continues ? 8 Does vaccines procedures used FBS in making of corona vaccines in any form, composition or ingredient made by Bharat Biotech, serum Insitute and approved by Indian Government or deparments ? 9 Is taking Vaccine have any adverse side effects or it is completely safe ? 10 How many peoples died by taking corona vaccine ? 11 What compensation will somebody be given if he or she have adverse reaction, disablity or death by vaccination? 12 Is indian government, health Department or vaccination manufacturer took responsibility of any deaths or adverse side effects of peoples who are taking vaccines ?
Request document *(if any)*	document not provided
Status	**REQUEST DISPOSED OF** as on 08/06/2021
Date of Action	08/06/2021
Remarks	**Reply :-** Point wise reply is as under: Point No. 1 & 2: All the ingredients, shelf life of approved COVID-19 vaccines are available in Summary of Product Characteristics (SmPC), package insert and factsheet and the same information is publicly available on CDSCO website i.e. www.cdsco.gov.in. Point No. 3 & 4, 9,10: CDSCO has no information in this regard. Point No. 5 to 7: Brief of clinical trial results/information containing safety, immunogenicity and efficacy results of approved COVID-19 vaccines of M/s Serum, M/s Bharat biotech and Dr. Reddys Laboratories are available in Summary of Product Characteristics (SmPC)/Package Insert/factsheet which are publically available on CDSCO website i.e. www.cdsco.gov.in. Point No. 8: As per information provided by firm, new born calf serum is used in revival process of Vero Cells which is used for the production of Corona Virus during the manufacturing of COVAXIN bulk vaccine of M/s Bharat Biotech. Point No. 11 & 12: There is no provision under Drugs and Cosmetics Act and Rules, there under for providing compensation due to side effects, disability and deaths after approval of Vaccines.

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